JUL 19 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Road, Ya' an street TIANJIN,300193
Phone number: 86-22-60526161
Fax number: 86-22-6052 6162
Contact: Yi Liu

Date of Application: 4/24/2013

2.0 Device information

Trade name: iHealth cloud
Common name: Patient Vital Signs Monitor Viewing Station
Classification name: Patient Vital Signs Monitor Viewing Station

3.0 Classification

Production code: DXN, NBW, MNW
Regulation number: 21 CFR 870.2770, 21 CFR 862.1345, 21 CFR 870.1130
Classification: II
Panel: 870 Cardiovascular, 862 Clinical Chemistry

4.0 Predict device information

Manufacturer: Watermark Medical
Device: Connected Care Clinical Application
510(k) number: K120320

5.0 Device description

IHealth cloud is a cloud based, web software system. It is accessed from commercially available PC systems with a web browser and minimum performance specifications consistent with typical PC hardware and equipment specifications. IHealth cloud accepts data both electronically as well as from manually input.

IHealth cloud is a medical device data system that displays and analyzes data received from iHealth home monitoring devices as well as manually input data. iHealth home monitoring devices include the apps and the device, such as KD-931, KD-936, KD-972 and Scale HS3

and HS5, AG-631, AG-632, AM3, PO3 and iHealth MyVitals.

6.0 Intended use

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

7.0 Performance summary

The software validation results demonstrated that the Clinical Application was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding Medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 19, 2013

Andon Health Co., Ltd
Yi Liu
President
No. 3 Jinping Road, Ya' An Street
Tianjin, China 300193

Re: K131203
Trade/Device Name: IHealth Cloud
Regulation Number: 21 CFR 870.2770
Regulation Name: Patient Vital Signs Monitor Viewing Station
Regulatory Class: Class II
Product Code: DXN, NBW, MNW
Dated: May 20, 2013
Received: May 30, 2013

Dear Yi Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Ihealth Cloud

Indication For Use:

IHealth cloud's intended use is to retrospectively display and analyze related medical data. The Web Application is not intended for emergency use or real-time monitoring.

Prescription Use Yes (21 CFR Part 801 Subpart D) And/Or Over the Counter Use Yes (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Digitally signed by Owen P. Faris -S
Date: 2013.07.19 16:15:42 -04'00'

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____